APR -7 2010

510(k) Summary of Safety and Effectiveness for the Dimension Vista® LOCI Digoxin Flex® Reagent Cartridge (K6435) and Dimension Vista® DRUG 4 Calibrator (KC460)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: K093441

B. Date of Preparation: October 30, 2009

C. Proprietary and Established Names:
Dimension Vista® LOCI Digoxin Flex® reagent cartridge, DIGXN (K6435)
Dimension Vista® DRUG 4 Calibrator, DRUG 4 CAL (KC460)

D. Applicant:
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E. Regulatory Information:
Dimension Vista® LOCI Digoxin Flex® reagent cartridge, DIGXN (K6435)
1. Regulation section: 21 CFR § 862.3320 Digoxin test system
2. Classification: Class II
3. Product Code: KXT
4. Panel: Toxicology

Dimension Vista® DRUG 4 Calibrator, DRUG 4 CAL (KC460)
1. Regulation section: 21 CFR § 862.1150 calibrator, multi-analyte mixture
2. Classification: Class II
3. Product Code: JIX
4. Panel: Clinical Chemistry

F. Predicate Device:
Method
Dimension Vista® LOCI Digoxin Flex® reagent cartridge, DIGXN (K6435), is substantially equivalent to the Dimension® Digoxin Flex® reagent cartridge, DGNA (DF35A), cleared under K94615.

Calibrator
Dimension Vista® DRUG 4 Calibrator, DRUG 4 CAL (KC460), is substantially equivalent to Dimension® Drug Calibrator, DRUG CAL (DC22B), cleared under K011035.

G. Device Description:
Method
The DIGXN method is a homogeneous, sequential, chemiluminescent immunoassay based on LOCI® technology. The LOCI® reagents include two synthetic bead reagents and a biotinylated $F(ab')_2$ fragment of an anti-Digoxin mouse monoclonal antibody. The first bead reagent (Chemibeads) is coated with ouabain, a weaker binding analog of digoxin, and contains a photosensitizer dye. In a first step, sample

is incubated with biotinylated $F(ab')_2$ which allows digoxin from the sample to saturate a fraction of the biotinylated $F(ab')_2$ that is directly related to the digoxin concentration. In a second step, ouabain chemibeads are added and form bead/biotinylated $F(ab')_2$ immunocomplexes with the non-saturated fraction of the biotinylated $F(ab')_2$. Sensibeads are then added and bind to the biotin to form bead pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from Sensibeads which diffuses into the Chemibeads, triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is an inverse function of the digoxin concentration in the sample.

Calibrator
The DRUG 4 Calibrator is a 5 level, liquid calibrator. It is packaged as a kit of ten vials, two vials per level (A, B, C, D and E), 2.5 mL per vial. The product matrix is human serum.

H. Intended Use:

Method
The DIGXN method is an *in vitro* diagnostic test for the quantitative measurement of digoxin in human serum and plasma on the Dimension Vista® System. Measurements of digoxin are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to help ensure appropriate therapy.

Calibrator
The DRUG 4 CAL is an *in vitro* diagnostic product for the calibration of the LOCI Digoxin (DIGXN) method on the Dimension Vista® System.

I. Substantial Equivalence Information:

The Dimension Vista® LOCI Digoxin Flex® reagent cartridge, DIGXN (K6435) and the Dimension Vista® DRUG 4 Calibrator, DRUG 4 CAL (KC460) were compared to the respective predicate devices, Dimension® Digoxin Flex® reagent cartridge, DGNA (DF35A), cleared under K94615 and Dimension® Drug Calibrator, DRUG CAL (DC22B), cleared under K011035. A comparison of the important similarities and differences between the devices is provided in the following tables:

Method

Similarities

Feature	Dimension Vista® LOCI DIGXN Flex® reagent cartridge (K6435)	Predicate Dimension® DGNA Flex® reagent cartridge (DF35A)
Intended Use	The DIGXN method is an *in vitro* diagnostic test for the quantitative measurement of digoxin in human serum and plasma on the Dimension Vista® System. Measurements of digoxin are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to help ensure appropriate therapy.	The DGNA method used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to measure digoxin, a cardiovascular drug, in human serum and plasma. DGNA test results are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to ensure appropriate therapy.

Sample Types	Serum and plasma	Serum and plasma
Measuring Range	<0.06 - 5.00 ng/mL	<0.06 - 5.00 ng/mL
Calibration Interval	30 days, same reagent lot	30 days, same reagent lot

Differences

Feature	Dimension Vista® LOCI DIGXN Flex® reagent cartridge (K6435)	Predicate Dimension® DGNA Flex® reagent cartridge (DF35A)
Assay Type	Chemiluminescent immunoassay based on LOCI® technology	Affinity particle mediated immunoassay
Measure-ment	measurement at 612 nm	Bichromatic rate (577 and 700 nm)
Antibody	Monoclonal Mouse Antibody	Rabbit Antibody
Sample Volume	10 µL	30 µL

Calibrator

Similarities

Feature	Dimension Vista® DRUG 4 Calibrator, DRUG 4 CAL (KC460)	Predicate Dimension® Drug Calibrator, DRUG CAL (DC22B)
Intended Use	The DRUG 4 CAL is an in vitro diagnostic product for the calibration of the LOCI Digoxin (DIGXN) method on the Dimension Vista® System.	The Drug Calibrator is an in vitro diagnostic product to be used to calibrate the Digoxin (DGNA), Lithium (LI), Phenobarbital (PHNO), Phenytoin (PTN), and Theophylline (THEO) methods on the Dimension® clinical chemistry system. The Drug Calibrator was designed to meet the needs of users to assure accurate results over the assay range of these methods.
Matrix	Human serum based	Human serum based
Form	Liquid stored at 2 - 8°C	Liquid stored at 2 - 8°C

Differences

Feature	Dimension Vista® DRUG 4 Calibrator, DRUG 4 CAL (KC460)	Predicate Dimension® Drug Calibrator, DRUG CAL (DC22B)
Analytes	digoxin	digoxin, lithium, phenobarbital. phenytoin, and theophylline
Volume	2.5 mL per vial.	3.0 mL per vial.
Typical Levels	Five Levels, (0.00, 0.60, 1.25, 2.50, and 5.30 ng/mL)	Five levels, (0.00, 0.60, 1.20, 2.50 and 5.00 ng/mL)

J. Method Performance Summary

Split sample method comparisons demonstrated equivalence between the Dimension Vista® DIGXN Flex® reagent cartridge assay and the Dimension® DGNA Flex® reagent cartridge assay as shown with the following correlation statistics:

Dimension Vista®	Predicate	Slope	Intercept	Correlation Coefficient (r)	n
DIGXN	Dimension® DGNA	1.02	- 0.04 ng/mL	0.98	116

Reproducibility testing was done in accordance with CLSI Guideline EP5-A2: Evaluation of Precision Performance of Clinical Chemistry Devices. For each test level, single tests from two independent cups were analyzed twice a day, for 20 days. The repeatability and within lab precision standard deviations (SD) and percent coefficient of variation (% CV) were calculated by the analysis of variance method. Typical precision for the Dimension Vista® LOCI DIGXN method is summarized below:

Material	Mean (ng/mL)	Repeatability SD	Repeatability %CV	Within Lab SD	Within Lab %CV
Level 1 QC	0.67	0.01	1.5	0.01	1.7
Level 2 QC	1.63	0.02	1.2	0.02	1.4
Level 3 QC	3.31	0.05	1.4	0.05	1.5
Level 1 serum pool	0.92	0.01	1.5	0.02	1.7
Level 2 serum pool	2.44	0.03	1.3	0.03	1.4

K. Conclusion:

The Dimension Vista® LOCI Digoxin Flex® reagent cartridge, DIGXN (K6435) and the Dimension® Digoxin Flex® reagent cartridge, DGNA (DF35A) are substantially equivalent based on their intended use and performance characteristics as described above.

The calibrator products, the Dimension Vista® DRUG 4 Calibrator (KC460) and Dimension® Drug Calibrator, DRUG CAL (DC22B) are substantially equivalent in design and intended use with their respective assay systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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Regulatory Affairs and Compliance Manager
P.O. Box 6101, Mailstop 514
Newark, DE, 19714-6101

APR 0 7 2010

Re: k093441
Trade Name: Dimension Vista® LOCI Digoxin Flex® reagent cartridge, DIGXN (K6435) and Dimension Vista® Drug 4 Calibrator, DRUG 4 CAL (KC460)
Regulation Number: 21 CFR 862.3320
Regulation Name: Digoxin test system
Regulatory Class: Class II
Product Codes: KXT, DLJ
Dated: February 18, 2010
Received: February 22, 2010

Dear Ms. Dillon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K093441

Device Name:
Dimension Vista® LOCI Digoxin Flex® reagent cartridge, DIGXN (K6435)

Indications for Use:

The DIGXN method is an *in vitro* diagnostic test for the quantitative measurement of digoxin in human serum and plasma on the Dimension Vista® System. Measurements of digoxin are used in the diagnosis and treatment of digoxin overdose and in monitoring levels of digoxin to help ensure appropriate therapy.

Prescription Use ___√___ **and/or**
(Part 21 CFR 801 Subpart D)

Over-the-counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K093441

Indications For Use

510(k) Number: K093441

Device Name:
Dimension Vista® Drug 4 Calibrator, DRUG 4 CAL (KC460)

Indications for Use:

The DRUG 4 CAL is an *in vitro* diagnostic product for the calibration of the LOCI Digoxin (DIGXN) method on the Dimension Vista® System.

Prescription Use ___√___ **and/or**
(Part 21 CFR 801 Subpart D)

Over-the-counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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